## Remarks

**Rejection of Claims and Traversal Thereof**

In the September 25, 2008 Office Action:

claims 1-3, 15-17 and 43 were rejected under 35 U.S.C. §112, first paragraph;

claims 34-36 were rejected under 35 U.S.C. §102 (a) and (e) as anticipated by US 6,451,567 (hereinafter Barclay '567); and

claims 1-3 and 43 were rejected under 35 U.S.C. §102 (a) and (e) as anticipated by or in the alternative under 35 U.S.C. §103 (a) as obvious over US 6,451,567.

These rejections are hereby traversed and reconsideration of the patentability of the pending claims is therefore requested in light of the following remarks.

**Rejection under 35 U.S.C. §112, first paragraph**

Claims 1-3, 15-17 and 43 were rejected under 35 U.S.C. §112, first paragraph because the Office believes that the specification fails to comply with the enablement requirement.

Applicants' claimed invention provides for shrimp having a DHA/EPA ratio greater than 1.0. As stated in the specification, it is important that the shrimp are fed a diet so that the levels of DHA are higher than EPA in the shrimp tissue. Importantly, higher levels of EPA are associated with reduced growth and increased bleeding time in humans, and thus, would not be beneficial to a human consuming such shrimp (see page 12, paragraph [045]). With this in mind, applicants developed aquaculturally-raised shrimp comprising a docosahexaenoic acid/eicosapentaenoic acid (DHA/EPA) ratio greater than 1.0 as described on page 12 of the specification.

In response to the September 25, 2008 rejection under section 112, applicants submit herewith a Declaration by Dr. David Kyle. In the enclosed Declaration (Appendix A) Dr. Kyle describes test results that clearly demonstrate that the use of such algal supplement causes an increase in the DHA levels

relative to the levels of EPA. The tissue of the shrimp was tested and the DHA/EPA ratio was increased from levels below 1 to a ratio of at least 1.1.

The results discussed in the attached 132 Declaration and set forth in Tables 1 and 2, recreated herein below for ease of discussion, show that after 4 weeks on the treatment diets the DHA content of the shrimp was significantly improved in an absolute amount, as well as relative to EPA, with a minimal effect on ARA levels. As a result the newly produced highly nutritional shrimp exhibited, in the tested tissue, a DHA/EPA ratio of greater than 1, as discussed on page 12 of the specification. Shown below in Table 1, the percent of DHA in the total amount of fatty acid in the tested tail muscle showed a marked increase in the level of DHA with a concurrent reduction in the level of EPA.

Table 1. Impact of inclusion of AquaGrow (AG) in the diet of shrimp on DHA, EPA and ARA content (% of total FAME) of tail muscle (A.) and ratios thereof (B.).

| A. | Inclusion of AquaGrow Gold in diet and % amounts of total FAME | | | | | B. | Inclusion of AquaGrow Gold in diet | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 0% | 20% | 33% | 50% | | | 0% | 20% | 33% | 50% |
| **ARA** | 4.1 | 5.5 | 6.0 | 6.1 | | **DHA/EPA** | 0.6 | 1.2 | 1.2 | 1.3 |
| **EPA** | 16.7 | 12.1 | 12.0 | 12.3 | | **DHA/ARA** | 2.5 | 2.6 | 2.4 | 2.5 |
| **DHA** | 10.1 | 14.2 | 14.6 | 15.4 | | **ARA/EPA** | 0.2 | 0.5 | 0.5 | 0.5 |

Further, the ratio of DHA/EPA was also increased beyond the control ratio of 0.6. Results in Table 2 show that the amount of DHA is increased in the shrimp tissue relative to the amount of EPA.

Table 2. Impact of inclusion of AquaGrow (AG) in the diet of shrimp on absolute content of DHA, EPA and ARA (mg FA/g tail muscle tissue) (A.) and ratios thereof (B.).

| A. | Inclusion of AquaGrow Gold in diet (mgFA/g tail muscle tissue) | | | | | B. | Inclusion of AquaGrow Gold in diet | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 0% | 20% | 33% | 50% | | | 0% | 20% | 33% | 50% |
| **ARA** | 0.3 | 1.0 | 0.7 | 0.8 | | **DHA/EPA** | 0.6 | 1.1 | 1.2 | 1.25 |
| **EPA** | 1.3 | 2.3 | 1.3 | 1.6 | | **DHA/ARA** | 2.4 | 4.0 | 3.9 | 3.7 |
| **DHA** | 0.8 | 2.7 | 1.6 | 2.0 | | **ARA/EPA** | 0.2 | 0.3 | 0.3 | 0.3 |

Results in Table 3 indicate that this result could be obtained in as little as 1 week of enrichment even at the lower dose of 20% inclusion in the feed.

Table 3. Impact of inclusion of AquaGrow (AG) at a level of 20% in the diet of shrimp for only 1 week on percentage and absolute levels of DHA, EPA and ARA in the shrimp tail muscle (A.) and on the ratios calculated based on either percentages or absolute amounts (B.).

| A. | % FAME | | mg FA/g tissue | | B. | % FAME | | mg FA/g tissue | |
|---|---|---|---|---|---|---|---|---|---|
| AG inclusion | 0% | 20% | 0% | 20% | AG inclusion | 0% | 20% | 0% | 20% |
| **ARA** | 4.1 | 3.6 | 0.3 | 0.5 | **DHA/EPA** | 0.6 | 1.3 | 0.5 | 1.3 |
| **EPA** | 16.7 | 11.2 | 1.3 | 1.6 | **DHA/ARA** | 2.5 | 3.9 | 1.6 | 4.0 |
| **DHA** | 10.1 | 14.0 | 0.8 | 2.1 | **ARA/EPA** | 0.2 | 0.3 | 2.1 | 0.3 |

Viewing the above-data in Table 3, it is evident that the amount of DHA in the tested tissue went from 0.8 mg/g of tissue to 2.1 mg/g of tissue which provided for a DHA/EPA ratio in the tested muscle tissue of 1.3 in only one week.

Applicants submit that the disclosure of the present invention is sufficient to enable those skilled in the art to practice the claimed invention. Accordingly, Applicants request that the Office reconsiders this rejection under section 112 and find that the specification is indeed enabling and withdraw this rejection.

**Rejection under 35 U.S.C. §102 (a) and (e)**

Claims 34-36 were rejected under 35 U.S.C. §102 (a) and (e) as anticipated by US 6,451,567. Applicants submit that Barclay '567 does not in anyway anticipate the presently claimed invention.

Claim 34, as amended herein recites the following:

> 34. A method of producing an Organic shrimp exhibiting a DHA/EPA ratio greater than 1, wherein the method comprises feeding to said Organic shrimp one or more components chosen from microalgae enriched with DHA and microalgal extracts enriched with DHA.

Anticipation under 35 U.S.C. § 102 requires the presence, in a single reference, of each and every element of the claimed invention, **arranged as in the claim**. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984). The method described in Barclay '567 fails to meet this standard. Clearly, it is evident that the cited reference does not mention or recognize the importance of a DHA/EPA ratio greater than 1.

As such, the Barclay '567 reference does not defeat the patentability of the presently claimed invention and applicants request the withdrawal of same.

**Rejection under 35 U.S.C. §102 (a) and (e)/103(a)**

Claims 1-3 and 43 were rejected under 35 U.S.C. §102 (a) and (e) as anticipated by or in the alternative under 35 U.S.C. §103 (a) as obvious over US 6,451,567. Applicants insist that Barclay '567 does not anticipate or render obvious the presently claimed invention.

The applicants' claimed invention relates to a method of feeding a shrimp to a human or non-human animal, comprising the step of providing for the animal's consumption a shrimp wherein the shrimp comprise docosahexaenoic acid/eicosapentaenoic acid (DHA/EPA) in a ratio greater than 1.0.

The cited reference teaches a multiplicity of different strains of microflora with no disclosure that the shrimp comprises a DHA/EPA ratio greater than 1.0. Notably, Example 12 of Barclay discusses that brine shrimp were fed thraustochytrid-based feed supplemental. However, it is important to recognize that the results of example 12 showed an increase in the levels of EPA relative to the DHA when the fatty acid content of the brine shrimp was tested as shown in Figures 7 and 8 and recreated below.

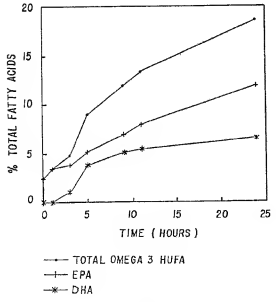


FIG. 7

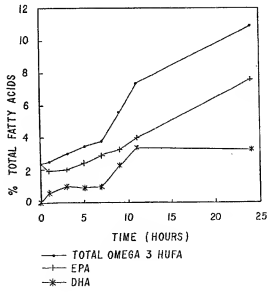


FIG. 8

It is very evident that the brine shrimp exhibited a much higher level of EPA (compared to the lower amount of DHA) in both Figures 7 and 8, and as such, could not possibly have exhibited a DHA/EPA ratio greater than 1. As such, this Barclay reference does not disclose the presently claimed invention and is not anticipatory.

Further, this Barclay reference does not render obvious the presently claimed invention. Initially as stated numerous times, the Barclay reference never recognizes the important of a DHA/EPA ratio of greater than one. Additionally, this Barclay reference provides no guidance or suggestion to go in that direction. Instead, the examples would suggest that inclusion of fatty acid in the brine tissue, wherein the EPA is in a higher amount, is acceptable because there is an overall increase in omega-3-HUFA, which is the result that Barclay was attempting to achieve.

It is well settled in the law and recently reiterated by the Board that discovery of an optimum value is not obvious if such a parameter was never recognized in the prior art. Clearly, Barclay teaches, from Figures 7 and 8, that a higher level of EPA in the shrimp is acceptable. The Office has not shown how one skilled in the art would have some apparent reason to modify Barclay. See *Ex Parte Whalen*, 89 USPQ2d 1078 (BPAI 2008).

Importantly, applicants have discovers the shrimp tissue having higher level of DHA relative to the level of EPA overcomes the negative problems of high EPA levels as discussed hereinabove.

Barclay provides a skilled artisan with the choice of at least 120 different strains but provides no guidance regarding a strain that may provide the correct ratio of DHA/EPA after consumption by a shrimp. This statement is further reiterated by the Office when the Office stated in the recently issued Office Action that "the state of the art hold that it is unpredictable whether any particular algae will cause an increase in DHA in shrimp fed the algae and the degree of the increase is also variable." Applicants agree that this reference does not provide any guidance that would lead to applicants' claimed invention. More important, this Barclay reference does not even recognize the importance of such an increase in DHA relative to EPA in the shrimp. The Office knows that obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert,* 28 USPQ2d 1955 (Fed. Cir. 1993). Further, the Office must recognize that inherency includes that the desired event must occur each and every time and the Barclay reference could not meet such requirements in light of the results shown in Figures 7 and 8. Applicants again remind the Office that Barclay never recognized the importance of the DHA/EPA ratio, and thus, such element was unknown.

Therefore, how could a skilled artisan make any modification to the teaching of Barclay to arrive at the present invention that possesses such heretofore unknown characteristic? Serendipity is not a valid basis for asserting obviousness.

In light of the above discussion, applicants request that all rejections be withdrawn.

**Petition for Extension and Fee Payable**

Applicants petition for a one month extension to extend the response due date of December 25, 2008 to January 25, 2009 and the fee of $65.00 is being paid herewith by electronic transfer. If any additional fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

**Conclusion**

Applicant has satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Bertoglio reconsider the patentability of the pending claims in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. If any issues remain outstanding incident to the allowance of the application, Examiner Bertoglio is requested to contact the undersigned attorney at (919) 286-8089.

Respectfully submitted,

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**APPENDIX A**